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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,628	11/13/2001	Ronald L. Ream	112703-203	4209
29156 7590 08/22/2007 BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER VENKAT, JYOTHSNA A	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/990,628

Applicant(s)

REAM ET AL.

Examiner

JYOTHSNA A. VENKAT Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of amendment filed on 6/7/07.

Claims 9- 26 are pending in the application and the status of the application is as follows:

Claim Rejections - 35 USC § 103

Claims 9-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent 4,317,838('838) and WO 99/44436 ('436).

Patent '838 teaches method for applying coating to chewing gum. See the abstract, see col.2, lines 35-68, wherein the patent teaches coating syrup using sweeteners or bulking agents. This is same as claimed taste masking agent. Patent at col.2, lines 40-55 teaches that sweeteners to be coated using various ingredients. This range disclosed in the patent for coating meets the claimed requirement of "coating comprising at least 50% of the chewing gum product". Patent at col.5, lines 10-19 teaches claimed high-intensity sweeteners. Patent at col.5, lines 6-8 teach that the high-intensity sweetener can be present in the gum base or in the coating Patent at col.5, lines 29-31 teach gum base and the amount present by weight. Patent at col.5, lines 55-60 suggests, "in addition to chewing gum, the comestibles to be coated may include... other dosage forms for medicinal or therapeutic use". Medicinal are same as medicaments. Thus patent clearly suggests to one of ordinary skill in the art that coating can also include medicaments. The difference between the patent and the instant application is patent does not have medicament in the coating along with sweetener. However, WO '436 teaches coated chewing gum comprising a core of chewing gum and a coating comprising a coating material and one or more active substances. See the abstract, see page 1 under "technical field", see also page 2. WO document at page 3, last paragraph teaches active ingredients, which can be sweeteners. WO document at

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page 8, lines 15-17 teaches claimed high-intensity sweeteners. See also page 8, lines 20-24 wherein WO document teaches that along with active substances other functional groups can also be incorporated. These functional groups include vitamins and nutrients along with various pharmaceuticals, which are described at paragraph bridging pages 9-10. WO document at page 12 first paragraph teaches that the coating suspension comprise aqueous solution of xylitol, maltitol, isomalt, aspartame, acesulfame K and saccharin. These ingredients are claimed as taste masking agent.

Accordingly it would have been obvious to one of ordinary skill in the art to make to prepare gum base (gum center) and coat the gum base using taste masking agent and high intensity sweetener taught by patent '838 and include in the coating medicament taught by WO '436 in analogous coated chewing gum preparations. The idea of adding medicament into the coating flows logically from the art since one prior art teaches chewing gum coating using taste masking agent and high intensity sweetener and another prior art teaches chewing gum coating using active substances (high intensity sweetener), functional substances (medicaments) or sugar or sugar alcohols (taste masking agent). One of ordinary skill in the art would be motivated to coat the gum center with a medicament along with taste masking agent with the reasonable expectation of success that having medicament in the coating provides a better stability of the active substance (medicament) and increased effect thereof in all chewing phases. This is a prima facie case of obviousness.

Response to Arguments

Applicant's arguments filed 6/7/07 have been fully considered but they are not persuasive.

Applicants argue:

“For example, Cherukuri fails to disclose or suggest a coating comprising at least 50% by weight of the product. Though the Patent Office alleges that Cherukuri does indeed disclose this limitation (see, Office Action, page 2), none of the weight percentages disclosed teach a coating comprising at least 50% by weight of the overall product. See, for example, Cherukuri, column 2, lines 40-55 ("by weight of the coating syrup"); column 3, line 50 - column 4, line 4 ("by weight of the dusting mix"); column 4, lines 50-55 ("by weight of the gum center"); column 4, lines 55-58 ("by weight of the coating"), and column 5, lines 43-47 ("by weight of the gum base"). Moreover, when actually referring to weight % coating in the total product, Cherukuri only discloses a level of 35% by weight coating in the coated chewing gum tablet. See, Cherukuri, column 4, lines 29-34 and column 7, lines 15-19”.

In response to the above argument applicant's attention is drawn to claim 9. See claim 9 below:

Claim 9 (currently amended): A chewing gum comprising: a gum center; and a coating comprising including a medicament that surrounds the gum center, the coating comprising at least 50% by weight of the chewing gum product, the medicament being designed to be delivered into the systemic system of a patient.

Thus the claimed chewing gum product has the gum center and coating that surrounds the gum center and the coating comprising at least 50% by weight of the chewing gum product. Specification at page 15 teaches, “ *pursuant to the present invention, the gum center may be based on a variety of different chewing gums that are known. For example, the gum center can*

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be low or high moisture, sugar or sugarless, wax containing or wax free, low calorie (via high base or low calorie bulking 10 agents), and/or may contain dental agents". Gum center has gum base and sugar See gum center at page 18 of the specification. Patent '838 also teaches gum center using gum base and sugar. See table 1 of patent. Patent at col.4, lines 25-29 teaches that the application of coating syrup and dusting mix are continued until the average gum piece weight reaches about 90% of the required coated weight. This meets claimed limitation of "the coating comprising at least 50% by weight of the chewing gum product".

Applicants also argue:

" Stahl (WO document) fails to remedy the deficiencies of Cherukuri. The Patent Office relies upon Stahl for arguably teaching a medicament in the coating along with a sweetener, an element the Office Action admits Cherukuri lacks. See, Office Action, page 3. Therefore, Stahl, like Cherukuri, still fails to disclose or suggest a coating comprising at least 50% by weight of the product".

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In conclusion, one of ordinary skill in the art would be motivated to coat the gum center with a medicament along with taste masking agent with the reasonable expectation of success that having medicament in the coating provides a better stability of the active substance (medicament) and increased effect there of in all chewing phases.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

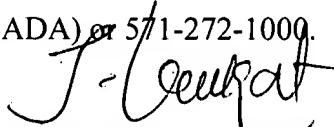
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


JYOTHSNA A VENKAT Ph. D
Primary Examiner
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